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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09 855,346	05 15 2001	Natarajan Ranganathan	KBI-0004	9305

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07 28 2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,346

Applicant(s)

RANGANATHAN ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-9 is/are rejected.
- 7) ☒ Claim(s) 4-5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicant's amendment files March 18, 2003 has been received and entered into the case. Claims 11 – 16 have been cancelled. Claims 1 – 10 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claims 4 and 5 are objected to because they depend from rejected claims.

Claim Rejections - 35 USC § 112

1. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 3 and 6 – 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Paul '099 in view of Ford.

Applicant claims a pharmaceutical composition comprising a probiotic, prebiotic and an ammonia-philic urea-degrading microorganism with high alkaline stability and urease activity, that is micro-encapsulated or enteric coated. The composition further comprises a water adsorbent selected from locust bean gum, psyllium fiber, guar gum and zeolite. The probiotic is a Bifidium or Lactobacillus, the prebiotic is a fructan oligosaccharide or and araban oligosaccharide and the ammonia-philic bacteria is selected from Bacillus pasteurii, Sporosarcina ureae, Bacillus species and Lactobacillus species KB-I. Alternatively, the probiotic and ammonia-philic urea-degrading microorganism is the same species.

Paul teaches a compositions comprising inulin, guar gum, fructo-oligosacchraides, and a bacteria selected from Lactobacilli and Bifidobacteria (abstract) for gastrointestinal health (col.1 line 27-32). Although the reference does not specifically teach the microorganisms are ammonia-philic and urea-degrading with high alkaline stability and urease activity, such characteristics are intrinsic to the named microorganisms of Paul.

Paul does not teach the composition encapsulated or enteric coated. However, Ford teaches that micro-encapsulating Lactobacilli protects the bacteria from gastric juices and allows them to reach lower intestines where they are therapeutically beneficial (col.2 line 40-56). At the

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time of the claimed invention, it would have been obvious to one of ordinary skill in the art to encapsulate the composition of Paul because it was common to do so as demonstrated by Ford. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by Ford and routine practice to encapsulate the composition of Paul, with a reasonable expectation for obtaining an effective composition for gastrointestinal health.

Applicant argues that Paul does not teach the composition for promoting GI health, and that the microbes are intended to bind with foreign antigens, bacteria or fungi. Applicant further argues that Paul does not teach coatings and Ford teaches coating that release bacteria, and that neither reference has a coating that prevents release of microorganisms.

However, these arguments fail to persuade because the claims are drawn to a composition which does not bind to digestive materials only. The claim language does not limit the claim to be without binding, but without binding digestive materials. Therefore, the fact that the composition of Paul does not bind to digestive materials would meet the limitation.

Regarding the coating, while applicant argues the composition of Ford is intended to release the bacteria, it is pointed out that Ford uses sodium alginate (encapsulation method A, col.4) and hydroxycellulose (method C, col.5), which are taught by applicant as suitable coatings for the instant composition (specification p.15). As such, it would appear that the coatings of Ford would achieve the desired effect as claimed and argued by applicant (specifically being substantially native in form, without binding digestive materials and preventing infection of the patient).

For the reason stated above, the claims stand rejected.

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Allowable Subject Matter

5. Claims 4 -- 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claim 10 is allowed.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

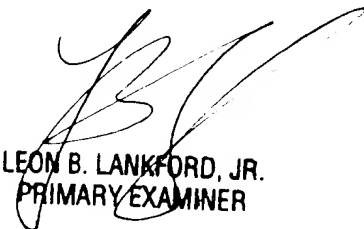
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); alt. F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
July 24, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER